11-08-05

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE respond to a collection of information unless it displace a collection of information unless it displace a collection.

October 29, 2003 Mahesh Chaubal
<del></del>
1015
1615
Simon Oh
IFT-5657A-1A1C6 (3360.0003.02)
_

		ENCLOSURES (Check all that app	oly)
Fee Trans	mittal Form	Drawing(s)	After Allowance Communication to TC
☐ Fee	Attached	Licensing-related Papers	Appeal Communication to Board of Appeals and Interferences
		Petition	Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After	r Final	Petition to Convert to a Provisional Application	Proprietary Information
Affid	avits/declaration(s)	Power of Attorney, Revocation Change of Correspondence Address	
Extension	of Time Request	Terminal Disclaimer	Other Enclosure(s) (please Identify below):
Express A	bandonment Request	Request for Refund	<ul><li>Forms PTO/SB/08A and /08B</li><li>40 cited references</li></ul>
Information	n Disclosure Statement	CD, Number of CD(s)  Landscape Table on CD	- Certificate of Mailing - Return Postcard
Document	(s)	Remarks	
	SIGNAT	URE OF APPLICANT, ATTORNEY,	OR AGENT
	On Outur	Manzo, Cummings & Mehler, Ltd.	
	TATALITY	<u> </u>	
	, ()		
Date	November 7, 2005		Reg. No. 26,306
	CE	RTIFICATE OF TRANSMISSION/M.	AILING
I hereby certify to sufficient postage the date shown	je as express mail إن an envelor	g facsimile transmitted to the USPTO or depo be addressed to: Commissioner for Patents, F	osited with the United States Postal Service with P.O. Box 1450, Alexandria, VA 22313-1450 on
Signature	1.5 Desial	Edwili	
Typed or printed	name Barbara Gesiakow	vski	Date November 7, 2005

This collection of information is required by 37 CFR 1.5 The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label No. EV643274635US
Date of Deposit November 7, 2005
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office Box Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop
Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450
NAME Barbara Gesiakowski
SIGNATURE D. Slesnalboustus

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## Certificate of Mailing Under 37 CFR 1.10

I hereby certify that the correspondence listed below is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, Label No. EV 643274635 US under 37 CFR 1.10 on November 7, 2005 and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:

- Transmittal Form PTO/SB/21 (1 sheet);
- 2. Information Disclosure Statement (3 sheets);
- PTO/SB/08A and /08B (4 sheets);
- Foreign Patent Documents and Non-Patent Publications (40 Documents)
- Certificate of Mailing (1 sheet); and
- 6. Return Receipt Postcard.

Name:	Barbara Gesiakowski
Signat	ure: B. Sparakowshi

PATENT

NOV 07 1005 E Atterney Docket No. <u>IFT-5657A-1A1C6 (3360-0003.02)</u>

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Do Annlication of.	
In Re Application of:	CERTIFICATE OF MAILING BY "EXPRESS
Mahesh Chaubal et al.	MAIL" "Express Mail" Mailing Label No. EV643274635US
Serial No.: 10/696,384	Date of Deposit November 7, 2005
Filed: October 29, 2003	I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office Box Addressee" service under 37 CFR 1.10 on
Group Art No.: 1615	the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450
Examiner: Simon Oh	NAME Barbara Gesiękowski
For: PROCESS FOR PRODUCTION OF ESSENTIALLY SOLVENT-FREE SMALL PARTICLES	SIGNATURE Describer
	<i>l</i>

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.97, Applicants hereby call the Examiner's attention to documents listed on the attached forms, which documents may be material to the examination of this application. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue

therefrom.

Copies of the U.S. patents and U.S. patent publications are not enclosed pursuant to the Office's waiving of the requirement under 37 C.F.R. \$1.98, paragraph (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication. Copies of the foreign patents and publications other than U.S. patents and U.S. patent application publications are enclosed, pursuant to 37 C.F.R. 1.98(2)(i) and (2)(ii).

No inference should be drawn that any apparatus or method disclosed is equivalent to the subject invention. Also, the citation of the above-discussed documents is not to be construed as an assertion that more pertinent art could not possibly be in existence. Citation of any document herein is not to be construed as an admission that any subject matter disclosed in the document is necessarily within the inventive field of endeavor, that any disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that any disclosure is otherwise necessarily prior art with respect to the instant invention.

Applicants also respectfully reserve the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosure of those documents discussed herein, that may be cited by the Examiner in rejecting a claim in the present patent application.

This Information Disclosure Statement is being submitted within three months of the filing date of the application or before the receipt of a first Office Action on the merits.

Consequently, as provided in 37 C.F.R. § 197(b)(1) or (b)(3), a fee under § 1.17(p) is not required for the filing of this information disclosure. However, if it is determined that an additional fee is required, then authorization is hereby granted to charge Deposit Account 50-1039 any additional fee required.

(A duplicate of this document is enclosed herewith.)

Respectfully submitted,

Date: November 7, 2005

By:

Raymond Mehler, Esq.

Registration No. 26,306 Cook, Alex, McFarron, Manzo,

Cummings & Mehler, Ltd. 200 West Adams St., Suite 2850

Chicago, IL 60606

Telephone: (312) 236-8500

Attorneys for Applicant

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

the Panerwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number

abstitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known Application Number 10/696,384 Filing Date October 29, 2003 First Named Inventor Mahesh Chaubal Art Unit 1615

(Use as many sheets as necessary

Sheet

	Simon Oh
Attorney Docket Number	FT-5657A-1A1C6 (3360-0003.02)

U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (if known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	1	US-4,606,670	08-18-1986	Frank et al.		
	2	US-5,885,486	03-23-1999	Westensen et al.		
	3	US-6,063,138	05-16-2000	Hanna et al.		
	4	US-6,207,178	04-10-2001	Westensen et al.		
	5	US-6,261,537	07-17-2001	Klaveness et al.	<del>.</del>	
	6	US-6,458,387	10-01-2002	Scott et al.		
	7	US-6,616,869	09-09-2003	Mathiowitz et al.		
	8	US-6,667,048	12-23-2003	Lambert et al.		
	9	US-2002/0048610	04-25-2002	Cima et al.		
	10	US-2003/0170279	09-11-2003	Lambert et al.		
	11	US-2003/0211083	11/13/2003	Vogel et al.		
	12	US-2004/0022861	02/05/2004	Williams		
	13	US-2004/0022862	02-05-2004	Kipp et al.		
	14	US-2004/0043077	03-04-2004	Brown		
	15	US-2004/0256749	12-23-2004	Chaubal	_	
	16	US-2005/0013868	01-20-2005	Brynjelsen et al.		
	17	US-2005/0037083	02-17-2005	Brynjelsen et al.		
-						
		<del></del>				
<del></del>	+					

Examiner Signature	Date Considered	
$\longrightarrow$	 	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Panerwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number

Complete if Known Substitute for form 1449A/PTO **Application Number** 10/696.384 INFORMATION DISCLOSURE Filing Date October 29, 2003 STATEMENT BY APPLICANT First Named Inventor Mahesh Chaubal Art Unit 1615 **Examiner Name** Simon Oh (Use as many sheets as necessary Attorney Docket Number 2 IFT-5657A-1A1C6 (3360-0003,02 Sheet

			FOREIGN F	PATENT DOCUMENTS	<u> </u>	
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Appear, etc.	Т5
	18	EP 0275 796 B2	07-27-1988	Centre Nat Rech Scient		Γ
	19	EP 0498 482 B1	08-12-1992	Sterling Winthrop Inc		Γ
	20	EP 0517 565 B1	12-09-1992	Fidia Sfa		Γ
	21	JP H2-306902	12-20-1990	Harmari Sangyo		Γ
	22	Patent Abst of JP H2-306902	12-20-1990	Harmari Sangyo		
	23	WO 92/17214 A2	10-12-1992	Ranney		Γ
	24	WO 94/07999 A1	04-14-1994	Univ Brown Res Found		Γ
	25	WO 95/33488 A1	12-14-1995	Quadrant Holdings Cambridge Ltd		Γ
	26	WO 97/03651 A1	02-06-1997	Danbiosyst UK		Γ
	27	WO 98/01162 A2	01-15-1998	Univ Johns Hopkins		Γ
	28	WO 98/14170 A1	04-09-1998	Sloan Kettering Inst		Γ
	29	WO 98/24450 A1	06-11-1998	Nilsson		Γ
	30	WO 99/00113 A1	01-07-1999	Vivorx Pharmaceuticals Inc		Γ
	31	WO 99/39700 A1	08-12-1999	Vectorpharma SPA		Γ
	32	WO 99/59550 A1	11-25-1999	Liposome Co.		Γ
	33	WO 00/06152 A1	02-10-2000	Novopharm Biotech Inc		Γ
	34	WO 01/21154 A2	03-29-2001	RTP Pharma Inc		Γ
	35	WO 02/82074 A1	10-17-2002	Chiron Corp		Γ
-	36	WO 02/80678 A1	10-17-2002	Schering Corp		Γ
	37	WO 03/45330 A2 & A3	06-05-2003	Onyuksel et al.		Γ
	38	WO 03/45660 A1	06-05-2003	BTG Int Ltd		Γ
	39	WO 04/103348 A3 & A3	12-02-2004	Baxter International		F
- Janes						H
		1				ı

Examiner Signature	Date Considered	
. <b>_</b>		

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

_				· ·		_
	(Use as many sheets as nece				Complete if Known	
					10/696,384	
	INFORMATION DISC	Application Number 10/696,384  Filing Date October 29, 2003  First Named Inventor Mahesh Chaubal  Art Unit 1615				
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	CANT	First Named Inventor	Mahesh Chaubal		
			Application Number 10/696,384  Filing Date October 29, 2003  First Named Inventor Mahesh Chaubal  Art Unit 1615  Examiner Name Simon Oh			
	(Use as many sheets as nec	Application Number 10/696,384  Filing Date October 29, 2003  First Named Inventor Mahesh Chaubal  Art Unit 1615  Examiner Name Simon Oh				
abla i	Sheet 3	of	4	Attorney Docket Number	IFT-5657A-1A1C6 (3360-0003.02)	$\neg$

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	40	ALLEN, T.M. et al., "Large unilamellar liposomes with low uptake into the reticuloendothelial system", Elsevier Science Publishers B.V., Vol 223, No. 1, pp. 42-46, October , 1987.				
	41	ALLEN, T.M. et al., "Effects on the murine mononuclear phagocyte system of chronic administration of liposomes containing cytotoxic drug or lipid A compared with empty liposomes", Vol 65, pp. 185-190, 1987.				
	42	AQUARO, et al. Antiviral Research 55, pp. 209-225, 2002.				
	43_	BENDER et al., "Efficiency of Nanoparticles as a Carrier for Antiviral Agents in Human Immunodeficiency Virus-Infected Human Monocytes/Macrophases In Vitro", Antimicrobial Agents and Chemotherapy, 40(6), pp. 1467-1471, June 1996.				
	44	CROWE, et al., Journal of Leukocyte Biology, pp. 635-641, November 2003.				
	45	FISCHER-SMITH, et al., Journal of NeuroVirology, 7, pp. 528-541, 2001.				
	46	GRAHAM, D.T., et al., "The Effects of Freezing on Commercial Insulin Suspensions", International Journal of Pharmaceutics, 1978.				
	47	KINMAN et al., Journal of Acquired Immune Deficiency Syndrome, 34(4), pp. 387-397, December 1, 2003.				
	48	LIMOGES et al., poster presentation, 11th Conference on Retroviruses and Opportunistic Infections, February 8-11, 2004.				
	49	MOGHIMI et al., Pharmacological Reviews, 53, pp. 283-318, 2001.				

$\overline{}$		
Examiner	Date	1
Signature	Considered	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Substitute for form 1449B/PTO		Complete if Known				
			Application Number	10/696,384		
	<b>INFORMATION DISC</b>	LOSURE	Filing Date	October 29, 2003		
	STATEMENT BY APP	PLICANT	First Named Inventor	Mahesh Chaubal		
(Use as many sheets as necessary)			Art Unit	1615		
			Examiner Name	Simon Oh		
S	neet 4	of 4	Attorney Docket Number	IFT-5657A-1A1C6 (3360-0003.02)		

NON PATENT LITERATURE DOCUMENTS				
Examiner   Cite   Include name of the author (in CAPITAL LETTERS), title of the article (when appropring magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue rand/or country where published.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²	
	50	NESBIT et al., Clinical and Diagnostic Laboratory Immunology, 9(3), pp. 515-524, May 2002.		
	51	NOTTET et al., The Neurology of AIDS, p. 55, 1998.		
	52	PERNO et al., The Journal of Infectious Diseases, 178, pp. 413-422, 1998.		
	53	SAWCHUK et al., Advanced Drug Delivery Reviews, 39, pp. 5-31, 1999.		
	54	SCHROEDER, H.G., "Distribution of Radiolabeled Subdivisible Microspheres after Intravenous Administration to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol 67, No 4, pp. 504-507, April 1978.		
	55	SHRAYER, D. et al., "Ceramide, a mediator of apoptosis, synergizes with paclitaxel to induce regression of the L3.6 human pancreatic carcinoma implanted in SCID mice", Journal of Clinical Oncology, Vol 22, No 14S (July 15 Supplement), 2004: 2135.		
	56	SOLAS et al., Antimicrobiology Agents and Chemotherapy, 47 (1), pp. 238-243, January 2003.		
	57	VON BRIESEN, H., "Controled Release of Antiretroviral Drugs", AIDS Rev., 2, pp. 31-38, 2000.		

Examiner	Date	
Signature	Considered	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.